

# Program: Serialization / Aggregation

**Duration:** 7 hours

**Training:** in-house

**Target audience:** Anyone involved in the serialization/aggregation process

**Prerequisites:** no prerequisites

Training accessible to people with disabilities

## Pedagogical objectives

- Understanding the regulatory context
- Understand the impact of implementing a serialization system on production
- Understand the impact of implementing a serialization system on information systems
- Understand the impact of implementing a serialization system on quality assurance
- How to structure a serialization IS specification

## Training content

- Understanding the regulatory context
  - o European regulation 2016/161 and related documents
  - o Serialization in the pharmaceutical world
- Understand the impact of implementing a serialization system on production
  - o Equipment to be installed
  - o Organization
- Understand the impact of implementing a serialization system on information systems
  - o What is an information system?
  - o Mapping of affected automated and computerized systems
  - o Computerized serialization systems
  - o The GAMP®5 computerized system project approach
- Understand the impact of implementing a serialization system on quality assurance
  - o Possible deviations
  - o Batch certification
  - o Claims
- How to structure a serialization IS specification
  - o Examples of solutions
  - o Computerized system compliance

## Training organization

**Speaker(s) :** Jean-Louis JOUVE or Christophe Fagard

## Teaching and technical resources

- Positioning questionnaire prior to training
- Training and regulatory documents.
- Theoretical input, case studies

- Participatory teaching
- Question-and-answer sessions

**System for monitoring and evaluating training results**

- Attendance sheets.
- Knowledge acquisition assessment test
- Training certificate.